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# Improving the standards-based management: recognition initiative to provide high-quality, equitable maternal health services in Malawi. An implementation research protocol

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## ABSTRACT

**Background:** The Government of Malawi is seeking evidence to improve implementation of its flagship quality of care improvement initiative—the Standards Based Management-Recognition for Reproductive Health (SBM-R(RH)).

**Objective:** This implementation study will assess the quality of maternal healthcare in facilities where the SBM-R(RH) initiative has been employed, identify factors that support or undermine effectiveness of the initiative and develop strategies to further enhance its operation.

**Methods:** Data will be collected in 4 interlinked modules using quantitative and qualitative research methods. Module 1 will develop the programme theory underlying the SBM-R(RH) initiative, using document review and in-depth interviews with policymakers and programme managers. Module 2 will quantitatively assess the quality and equity of maternal healthcare provided in facilities where the SBM-R(RH) initiative has been implemented, using the Malawi Integrated Performance Standards for Reproductive Health. Module 3 will conduct an organisational ethnography to explore the structures and processes through which SBM-R(RH) is currently operationalised. Barriers and facilitators will be identified. Module 4 will involve coordinated co-production of knowledge by researchers, policymakers and the public, to identify and test strategies to improve implementation of the initiative.

**Potential impact:** The research outcomes will provide empirical evidence of strategies that will enhance the facilitators and address the barriers to effective implementation of the initiative. It will also contribute to the theoretical advances in the emerging science of implementation research.

## INTRODUCTION

This project addresses a key concern of the Malawian Ministry of Health (MOH), namely, the persistence of a high maternal

mortality ratio (MMR) of 675/100 000 live births despite a facility birth rate of 73%.<sup>1</sup> With the goal of reducing MMR to 155/100 000, the MOH wants to understand how interventions aimed at enhancing quality of care that have proven effectiveness in other settings, specifically the Standards Based Management-Recognition for Reproductive Health (SBM-R(RH)) initiative, can be successfully implemented in Malawi.

In 2000, the Government of Malawi adopted the facility birth strategy and implemented a number of evidence-based interventions aimed at providing high-quality, facility-based maternal healthcare. Subsequently, antenatal coverage and the proportion of births taking place in a facility both increased.<sup>1</sup> However, even as the facility birth rate has risen, morbidity and mortality rates have been slow to fall. The most common causes of maternal deaths in Malawi today are haemorrhage, sepsis and hypertensive disorders, all of which require high-quality emergency obstetric care (EmOC). An audit of maternal deaths found that the majority of these deaths take place in facilities, indicating that the facilities are either not providing the necessary care or the quality of care is suboptimal. Poor quality of care is recognised to be a major contributing factor to maternal morbidity and mortality.<sup>2–3</sup> Poor quality care can also deter women and their families from seeking timely care, with delays in maternal healthcare-seeking being a major determinant of poor outcomes.<sup>2–4</sup>

To improve quality of maternal health services, the government focused on three key, but inter-related strategies: (1) increasing the number of health facilities designed to provide basic and comprehensive EmOC services;<sup>5</sup> (2) increasing the quantity and quality

of human resources by expanding the number of cadres trained and authorised to perform EmOC signal functions<sup>5</sup> and (3) adopting the SBM-R(RH) initiative. Adoption of SBM-R(RH) reflected the recognition that efforts to scale up service availability will fail to achieve the desired outcomes if the quality of services remains poor.

Quality of care is a multifaceted concept and most definitions include elements of facility readiness, clinical competence, adherence to professional standards and women's experience of care, with the recognition that communication and trust between patient and practitioner are key mediators of good outcomes. Hulton *et al*<sup>6</sup> defined quality of maternal healthcare as 'the degree to which maternal health services for individuals and populations increase the likelihood of timely and appropriate treatment for the purpose of achieving desired outcomes that are both consistent with current professional knowledge and uphold basic reproductive rights'. Engender Health added the notion of the right of healthcare providers to support and resources that will enable them to provide this high-quality care.<sup>7</sup>

The SBM-R(RH) is, theoretically, an adaptation of the widely known Plan-Do-Study-Act cycle of quality improvement.<sup>8</sup> Falling into the category of the 'standardisation' type of quality improvement methodology, the initiative consists of a systematic and effective use of operational performance standards as the basis for organising and functioning of health services. It follows four basic steps: (1) setting objective, clear performance standards for a defined service delivery area; (2) implementation of these standards; (3) measuring their progress and (4) recognising achievement. Although not clearly articulated, such an approach aims to develop a 'culture of quality of care'.<sup>9</sup> According to Raven *et al*,<sup>9</sup> the 'culture of quality of care' is a key prerequisite for successful quality improvement. This 'culture' is best created by involving all members of staff, which leads to a sense of ownership and commitment.<sup>9</sup> It also ensures systems and processes are maintained, as poor quality is often the result of poorly designed operational processes or of problems in their implementation, rather than being the fault of individuals.<sup>10</sup>

The SBM-R(RH) approach has been implemented, with some modifications, in Brazil and Guatemala. An evaluation of the PROQUALI—a pilot initiative aimed at improving the quality of reproductive health (RH) services in public sector primary healthcare facilities in Brazil—showed significant improvement in service quality in all five participating units.<sup>11</sup> Performance improvements were most substantial in facilities that were performing at moderate-to-high level at baseline and that had a champion in a position of authority.<sup>11</sup> Similarly, results of initial implementation of the CaliRed accreditation programme in Guatemala were impressive: facilities' achievement of performance criteria increased from an average of 18% of their criteria to an average of 51% over a 6–9-month period.<sup>12</sup>

However, a literature search does not provide any evidence of the success of these programmes beyond pilot stages. It is not known if these initial successes in the pilots were observed more widely, nor whether they were sustained over time, if/when the programmes were rolled out at the national level.

In Malawi, the SBM-R(RH) initiative is led by quality improvement support teams (QISTs) at the national, district and facility levels. A set of national RH service delivery guidelines and performance standards that healthcare organisations are expected to meet have been established. Facilities that meet these performance standards are 'accredited' by the MOH. The QISTs are expected to identify gaps between actual and desired performance, and devise detailed action plans to address these gaps. An evaluation of the SBM-R(RH) initiative in 2009 showed that intervention facilities were more likely than comparison facilities to have the needed infrastructure, equipment, supplies and systems in place to offer RH services.<sup>6</sup> However, performance standards—measured as scores against established verification criteria—showed that while the quality of family planning and postnatal care had improved, there had been no change in the quality of antenatal nor of labour and delivery care.<sup>13</sup>

Given the SBM-R(RH) initiative is evidence-based and has demonstrated success in a number of other countries, questions rise regarding its implementation within the Malawian context.<sup>8 13</sup> While the evaluation of the SBM-R(RH) initiative<sup>6</sup> did suggest facilities' lack of ability to rapidly assess women for complications and poor prioritisation in admission,<sup>13</sup> the authors provided limited information on what wider institutional or societal factors may have played a role in this somewhat sub-optimal performance of the initiative. Lobis *et al*<sup>14</sup> found ineffective use of nurses and midwives trained to provide EmOC, but the study did not explore the specific reasons for such practices. Rawlins *et al*<sup>13</sup> suggested inexperienced providers and high staff turnover as one possible reason for the suboptimal performance of the SBM-R(RH) initiative, but did not confirm this assertion with detailed data. There has, to date, been no comprehensive exploration of the implementation of SBM-R(RH) processes.

## RESEARCH OBJECTIVES AND QUESTIONS

With the intention to support Malawi 2011–2016 Health Sector Strategic Plan's aim to strengthen and systematically improve the quality of its RHcare services, the proposed research adopts a co-production/partnership model to generate specific understanding of how to enhance the SBM-R(RH) initiative to improve the quality of maternal healthcare. The specific objectives of the study are:

1. Develop a programme theory of the SBM-R(RH) initiative and identify both explicit and implicit assumptions embedded within it.

2. Identify the gaps between the SBM-R(RH) programme and the ground reality across the range of contexts that characterise the Malawian healthcare landscape.
3. Co-produce and test potential solutions to improve the effective implementation of the SBM-R(RH) initiative to enhance quality and equity of care provided in the health centres.
4. Identify routes through which an equity dimension can be embedded within the SBM-R(RH) initiative.
5. Develop an enhanced interdisciplinary research capacity in the emerging field of implementation research, in Malawi, Kenya and Canada.

The research will answer the following questions:

1. What is the quality of maternal healthcare provided at facilities after implementation of the SBM-R(RH) initiative? What patterns of inequity exist?
2. What factors operating within the Malawian healthcare system and wider social setting moderate the impact of the SBM-R(RH) initiative on quality improvements as it is rolled out at the facility level?
3. How does the SBM-R(RH) programme theory relate to the real-life factors that moderate the implementation of the SBM-R(RH) intervention? What areas of misalignment are evident?
4. How can the barriers be overcome to improve implementation of the SBM-R(RH) initiative? What strategies can improve successful implementation?
5. How can SBM-R(RH) deliver quality improvements that benefit women currently least likely to receive high-quality maternal healthcare?

## METHODS

### Theoretical framework

We will draw on a revised version of the Promoting Action on Research Implementation in Health Services (PARIHS) framework.<sup>15</sup> PARIHS is a widely used theoretical framework that provides a 'map to enable others to make sense of the complexity of implementation of an initiative, and the elements that require attention if implementation is more likely to be successful'.<sup>15</sup> PARIHS conceives three interacting elements as key factors that influence successful implementation: evidence, context and facilitation. Evidence (E) is the 'codified and non-codified sources of knowledge', as perceived by multiple stakeholders; context (C) is the quality of the environment or setting in which the evidence-based initiative is implemented and facilitation (F) is the 'technique by which one person makes things easier for others', achieved through 'support to help people change their attitudes, habits, skills, ways of thinking and working'.<sup>15</sup> PARIHS framework is useful as a tool to diagnose critical elements related to implementation of an intervention (the E and C), and from there develop an implementation strategy (F) to enable successful and sustained change. A PARIHS-based diagnostic analysis can additionally engage stakeholders in

self-reflection regarding critical aspects of implementation and the related nature of needed change.<sup>15</sup>

### Study design and methods

Using a simultaneous mixed-method design,<sup>16</sup> and drawing on a range of quantitative and qualitative methods, data will be collected in four interlinked modules over a 54-month period.

- Module 1 will address research question 1 by developing the programme theory underlying the SBM-R(RH) initiative.
- Module 2 will address research question 2, and assess the current quality and equity of maternal healthcare provided in health centres and hospitals after implementation of the SBM-R(RH) initiative.
- Module 3 will explore in detail the processes through which SBM-R(RH) is currently operationalised on the ground to understand the interplay between: *evidence* (ie, the initiative and its associated knowledge base plus other competing and complementing knowledge), *context* (ie, characteristics of the Malawian healthcare system and wider social setting) and *facilitation* (ie, the ways in which the initiative is currently rolled out and supported at national, regional and local level).
- Module 4 is a cross-cutting module involving coordinated co-production of knowledge by researchers, policymakers and the public across the life of the project to address study objectives 5 and 6.

### Study sites

The study will involve investigation of the SBM-R(RH) initiative at the district facility and policy/management level.

1. *Facilities*: The selection of facility sites was purposive and guided by the following considerations:
  - A. Duration of the implementation of the SBM-R(RH) initiative: ensure selected facilities have implemented the SBM-R(RH) initiative for at least 3 years.
  - B. SBM-R(RH) performance: ensure representation of facilities that have attained accreditation and those that have not.
  - C. Health facility ownership: ensure representation of MOH and Christian Health Association of Malawi (CHAM) facilities.
  - D. Geographic location: ensure representation of rural and urban facilities.
  - E. Level of health facility: ensure that all levels of care (health centres, district, CHAM and tertiary hospitals) are represented.

This led to selection of districts Blantyre, *Mulanje*, Ntchisi and Rumphi. Mulanje, Ntchisi and Rumphi are rural while Blantyre is an urban district. Within these districts, two health centres (Rumphi and Ntchisi), a district-level CHAM hospital in *Mulanje* and tertiary level in Blantyre (Queen Elizabeth Central Hospital, accredited) were selected. Data for modules 2 and 3 will be collected from all four sites.

2. *Policy and management level*: This investigation will be conducted in the MOH in Lilongwe and the District Health Offices of the above districts. At the national level, there exists a Quality Assurance Technical Working Group (QATWG) that is responsible for providing policy guidance on quality assurance matters. At the district level, the QIST is responsible for planning quality assurance activities at the hospital, orienting members of staff and guardians on performance quality improvement, and conducting quarterly monitoring of implementation.

(1) *Module 1* will develop the SBM-R(RH) programme theory. Programme theory is a ‘construction of a plausible and sensible model of how a programme is supposed to work’ and ‘provides causal links between the operation of the programme and its intended effects’.<sup>17</sup> Corresponding to the ‘E’ (evidence) in the PARHIS framework, this module will explicate, in all its complexity, the elements and processes of the SBM-R(RH) initiative. It will articulate the design of the initiative, processes, inputs, outputs, outcomes and costs of the initiatives. Data will be collected through a document review and in-depth interviews with key informants among national-level and district-level policymakers and programme managers. Documents to be reviewed include the peer-reviewed and grey literature related to quality of care, and specifically the SBM-R(RH) initiative; MOH policy and planning documents (Malawi Health Sector Strategic Plan 2011–2016, the MOH National Reproductive Health Strategy 2006–2010, Malawi 2010 EmONC Needs Assessment Report; MOH Malawi Integrated Performance Standards for Reproductive Health); minutes of meetings and consultancy evaluations. As aspirational documents, policy and planning documents are a key source of ‘deliberate and conscious statements of policies and strategies at particular points in time and can at the very least be regarded as public avowals of commitment to certain objectives and even values’. In-depth interviews will be conducted with 20 programme policymakers and managers, using a semistructured guide. These will include MOH Directors of Reproductive Health, Planning and Policy Development (MOH), and Nursing. In addition, international organisations and donors directly associated with the SBM-R(RH) initiative, specifically Jhpiego and US Agency for International Development (USAID) personnel, will also be interviewed. A research assistant with training in policy analysis and anthropology at the Masters level will collect the data.

*Data analysis*: An interpretative analysis of all documentary sources and interview transcripts will be undertaken. A content analysis will be conducted using the computerised textual analysis package, Atlas-ti, to delineate the SBM-R(RH) programme theory and tease out the assumptions embedded in it. Using the Aetiologic Theory Structuring Guide approach, a logical model will be developed.<sup>18</sup> The analysis will also uncover latent meanings in overt and explicit policy statements, and in

the government’s priorities, incentives and governance structures. The rhetoric of the policy environment and policy intentions will also be explored.

(2) *Module 2*: A key aspect of the SBM-R(RH) initiative is continual measurement of performance standards to guide further improvements. The Malawi MOH has set Integrated Performance Standards for Reproductive Health (MIPS). Facilities routinely collect data to populate these indicators. Given that the quality of these data is critical in determining further improvements in quality of care, there is surprisingly little emphasis on ensuring and measuring the quality of the data. Also, these standards focus entirely on provision of care. Given women’s actual experience of care is an important contributor of maternity outcomes and little is known about how quality of care (access, experience and outcomes) varies by key axes of diversity and inequality within Malawi, module 2 will assess both provision of care and women’s experiences of care. These data will also provide a baseline for assessment of impact of pilot changes in module 4. Drawing on the Hulton *et al*’s<sup>6</sup> Quality of Maternal Health Care Framework, this module will assess the following:<sup>6</sup>

#### 1. Provision of care

##### 1.1. Facility readiness:

- 1.1.1. *Physical infrastructure*: adequacy of the buildings, medical and non-medical equipment, furniture, and water and electricity supplies. Are the maternity wards adequately equipped to perform their function effectively? Does the design of the labour room respect women’s privacy?
- 1.1.2. *Human resources*: availability of healthcare providers both in terms of skill-mix and numbers. Are the skill-mix and numbers appropriate to cope with the case-mix of births and patient load?
- 1.1.3. *Drugs*: Are essential drugs available, how often do stock-outs occur?
- 1.1.4. *Laboratory*: Is there a laboratory, does it have the skilled personnel, materials and equipment to conduct the required tests?
- 1.1.5. *Blood bank*: Is there a blood bank? Is it stocked?

##### 1.2. *Work processes*: this will assess:

- 1.2.1 *Provider adherence to standardised criteria of care*: a key element of quality of care aimed at ensuring best possible biomedical outcomes requires provider adherence to evidence-based clinical protocols.
- 1.2.2 *Referral systems*: availability of referral protocols, an effective transport system, efficient communication and cooperation between the referral chains.
- 1.2.3 *Management systems*: number of providers and their job descriptions, maintenance of records, existence and functionality of



supply chain for RH materials and supplies, mechanisms for forecasting RH materials and supply needs, and procedures for timely requisition of materials and supplies.

2. *Women's experience of care.* four broad areas will be assessed:

2.1 *Woman's experience of human and physical resources:* the woman's satisfaction with the state of the facility (bed, sheets, toilet, food, etc), contact time with qualified staff and care provided will be assessed.

2.2 *Woman's experience of communicating with the providers:* Was the woman informed of the need for specific interventions; was the patient-provider communication characterised by privacy, confidentiality, informed choice, concern, empathy and sensitivity?

2.3 The respect, dignity and equity of care she received.

2.4 The emotional support she received; was she ever left alone, did she feel afraid?

Data will be collected using a range of methods:

1. To assess *facility readiness* (physical infrastructure, blood banks, numbers of staff on duty; types of services available, availability of essential drugs and supplies), structured observations will be undertaken using the Malawi MIPS checklists.

2. To assess *provider adherence to standardised criteria of care*, structured clinical observations will be conducted in three areas: antenatal care (ANC), labour and delivery, and postnatal care (PNC). Sample size was calculated assuming a conservative 50% of the performance standards in each area met 80% of the verification criteria, the level at which facilities receive recognition and accreditation.<sup>13</sup> A sample size of 384 will produce a two-sided 95% CI with a precision of 5%.<sup>19</sup> A patient-provider observation will constitute a unit of analysis. Using Malawi MIPS checklists, the following data will be collected:

2.1 Three hundred and eighty-four moment-in-time patient-provider antenatal interactions will be observed in the four healthcare settings (150 in Queen Elizabeth Hospital, 120 in Mulanje District Hospital and 120 in the two health centres). Assessors will note whether the verification criteria of ANC performance standards were met. Did the provider offer a cordial reception and treatment, take a medical history, and provide HIV testing and counselling?

2.2 Three hundred and eighty-four women who come to deliver in the four healthcare settings (150 in Queen Elizabeth Hospital, 120 in Mulanje District Hospital and 120 in the two health centres), will be traced from their entry into the system until they leave the facility. The points of observation will include, but not be limited to, the provider's language and

behaviour towards the patient and her family, time spent with each patient and whether patients' concerns are addressed. All 20 standards of labour and delivery will be assessed.

2.3 Twenty women experiencing a complication or adverse outcome in health centres (80 in total) will be assessed to document adherence to standards for complications and functioning of the referral system if applicable.

3. To assess *women's experiences of care*, exit interviews will be conducted with the 384 women observed above (ratio 3:2:1:1 (central hospital:district:HC:HC)) using a standardised questionnaire. Women's experiences and satisfaction with the care provided will be assessed.

Data will be collected by clinical experts, preferably nurses who do not work in the study sites. They will be provided training on RH clinical standards (SBM-R(RH) standards), and on how to use assessment tools and objective scoring to foster inter-rater reliability. Participants will be recruited in the following manner: nurses working in health facilities will approach women who meet the recruitment criteria, explain the purpose of the research, using information sheets, and invite them to participate in the study. If they agree, signed consent will be obtained

*Data analysis:* To assess facility readiness and provider adherence to MOH performance standards, data will be analysed by assigning a score to each verification criterion within each performance standard in all three service areas. A summary score will be created for each performance standard. To obtain a quantitative measure of the current quality of care, proportions of standards that meet 80% of verification criteria will be calculated. These indicators will be compared with data collected by the facility. Any variations will be explored further in module 3. Women's exit interview data will be analysed to explore the proportion of women satisfied with different elements of care they received, and how women's experiences of care vary by axes of diversity and inequality (socioeconomic class, ethnic and tribal identity) within Malawi.

(3) *Module 3:* Drawing on the PARIHs framework, this module will identify the interplay of the 'E' (evidence), 'C' (contextual factors) and 'F' (facilitators) operating within the Malawian healthcare system and wider social setting that moderates the impact of the SBM-R(RH) initiative on quality improvements as it is rolled out at the facility level.<sup>15</sup> An organisational ethnography (OE) will be conducted. OE is increasingly recognised as a powerful tool within implementation research in general, and in quality of care studies in particular.<sup>20</sup> The ethnographic approach, with its emphasis on studying individuals and groups in their natural setting, is particularly suited to addressing research question 3, which aims to identify the contextual factors operating within the Malawian healthcare system and wider social setting that moderate the impact of the SBM-R(RH) initiative on

quality improvements as it is rolled out at the facility level. OE will enable us to decipher whether there was leadership support for implementation of the initiative, and what other aspects of facilitation were/were not in place, such as: What resources were provided? If necessary resources were not provided, what were the reasons? Is there a 'culture of quality' at the facility level? What does this 'culture of quality' mean to the health workers and managers? If the culture of quality is missing, why is it missing? Is there 'receptivity' to the initiative from the facility staff? The data will be collected in four inter-linked and overlapping phases; insights from each phase (and earlier quantitative work from module 2) will refine and inform the research questions and methods of the next, thus increasing focus and depth as the project progresses.

**Phase 1:** The two main methods used in this phase will be participant observation and informal interviews.<sup>21</sup> Participant observation, a key characteristic feature of the ethnographic approach, is a method of data collection in which the researcher observes the people as they go about their daily work.<sup>22</sup> Underlying the method is the belief that knowledge *about* a social setting is different from *understanding* it, and that the latter can only be determined and obtained by prolonged immersion in the setting.<sup>22</sup> The researchers (see below) will spend 4 months in each facility (total 16 months) observing the visibility and prominence of the SBM-R(RH) initiative, and recording the various activities that constitute day-to-day work of the healthcare providers and staff. Informal conversations will constitute 'informal interviews'.

**Phase 2:** This phase will explore in greater depth the experiences of managers, healthcare providers and staff in providing the quality of care expected by using semi-structured in-depth interview and focus group discussions. The focus of this exploration will be on assessing how receptive the health facility context was in absorbing the SBM-R(RH) initiative. Do the power and authority processes promote everybody's involvement in decision-making? Does the initiative fit in the providers' and managers' strategic goals, both professional and personal? Does the 'logic' or knowledge base on which the initiative is founded fit with or clash with key stakeholders' own understandings of what and how services should be improving? Do they feel that sufficient resources—human, financial and equipment—were provided to enable them to perform their job properly? Individual and group interviews are useful methods for exploring providers' understanding and interpretations of quality of care, the language they use in constructing the discourse and the issues they face in providing care.<sup>23</sup> Sample size in qualitative research is difficult to specify in advance. However, considering that 12 interviews are usually enough to reach data saturation, we estimate we will need to conduct about 20 in-depth interviews with all healthcare providers—physicians, midwives and nurses.<sup>24</sup> Three focus group discussions in

each facility (4), with 5–7 participants in each, will also be held, separately for managers/doctors, nurses/midwives and other staff. By this stage, the research team will be familiar with the staff in facilities and will purposefully select participants who are willing to speak openly about the strengths and challenges of implementing the SBM-R(RH) initiative. Guidelines for the interviews and focus group discussion will be based on data collected during phases 1 and 2, with reference to the research objectives.

**Phase 3:** Will assess women's experiences of care, an important dimension of quality of care. Even if the provision of care is deemed high quality against recognised standards of good practice, it might be unacceptable to the woman and her family, and vice versa. Three broad areas will be assessed: their impression of the adequacy of human and physical resources, their understanding of the usefulness of the procedures they undergo, the respect they are accorded, and their sense of dignity, equity and the emotional support they receive. Thirty in-depth exit interviews separately with mothers, their husbands and other family members will be conducted in each facility, using semistructured guides.

**Phase 4:** Crises, such as a birth complication and death, tend to bring forth issues in quality of care that may otherwise not be obvious during day-to-day operations. Using the 'near-miss' approach, 20 women who experienced a birth complication will be identified and a 'critical incident analysis' conducted to understand why the critical care was not provided at required quality.<sup>25 26</sup> Where did the system break down? This information will highlight elements of the SBM-R(RH) initiative that need strengthening or have simply been overlooked. Women's experiences will include an assessment of their impression of the adequacy of human and physical resources, their understanding of the usefulness of the procedures they underwent, and the respect and emotional support they were accorded. Interviews will be conducted with women, their families, healthcare providers involved in their care and facility managers.

Data will be collected by two medical anthropologists trained at the Masters level. They will be supported by clinical experts to ensure they are aware of what they are looking for. Data validity will be ensured by triangulation of methods and respondent validation.

**Data analysis:** The qualitative data will be collected in *Chichewa*, using audio recorders and by detailed note-taking. A database of *translated* and transcribed interviews, focus groups and observation notes will be created in Atlas-ti.<sup>27</sup> Using a social constructivist and critical interpretative approach, and drawing on the PARIHS framework, data will be coded and categorised.<sup>28</sup> The categories will be queried for patterns and insights into the leadership's and facility staff's understanding of 'quality of care', the barriers to implementation of the SBM-R(RH) initiative and what would improve its implementation equitably. Alignment of understanding of what constitutes quality care between leadership/

management, healthcare providers and women, will be explored. Interpretive accuracy will be assessed by peer debriefing within the research team and among other colleagues, as well as respondent validation, as an ongoing activity.<sup>28</sup>

(4) *Integration and synthesis*: Data from the three modules will be integrated and synthesised to:

1. Develop a programme theory of the SBM-R(RH) initiative, identifying both explicit and implicit assumptions embedded within it, and the gaps between the theory and the ground reality.
2. Identify the barriers and facilitators to implementation of the SBM-R(RH) initiative.
3. Understand the links between inequities in quality of care experienced by women seeking care in facilities and implementation of the SBM-R(RH) initiative.

(5) *Module 4*: Having generated a detailed understanding of the current situation with respect to the implementation of SBM-R(RH) across the Malawian maternal healthcare system, the goal of module 4 will be to begin to improve tailoring of the SBM-R(RH) to the Malawian context. The module will include the identification and piloting of potential routes to enhancing enablers and/or circumventing current obstacles. This will include:

1. Conducting deliberative workshops. These workshops, detailed in heading 5, will, adopting the Plan-Do-Study-Act approach:
  - 1.1 Identify candidate solutions, considering short-term and long-term processes, and both upstream and downstream processes.
  - 1.2 Establish prioritisation criteria, which may include potential for improvement and ease of implementation, and to identify local obstacles.
2. Select 2–3 priority modifications to pilot at a local level.
3. Identify more systemic issues that require a longer term strategy. This will include:
  - 3.1 Developing a ‘proof of concept’ piloting plan. We will define the purpose, goals and objectives (Which element of the SBM-R(RH) are we trying to adjust?), articulate the ‘logic’ of the proposed modifications and establish success criteria.
  - 3.2 Define the scope and duration of the pilot (we anticipate these to be relatively quick development cycles, no more than a few weeks).
  - 3.3 Develop a clear work plan for successful implementation of the modification(s).
  - 3.4 Identify and minimise any risks to the pilot.
  - 3.5 Determine a monitoring system.
  - 3.6 Implement the strategy.
  - 3.7 Evaluate effects (quantitatively and qualitatively).
4. Develop a forward-looking plan for subsequent Plan-Do-Study-Act cycles; the project should have developed internal capacity to lead and deliver these in future without the need for external assistance.

See [table 1](#) for a summary of all objectives and related data collection methods.

## ANTICIPATED ACHIEVEMENTS OF THE RESEARCH

1. The research will explicitly articulate the currently implicit programme theory underlying the SBM-R (RH) initiative in the context of the Malawi healthcare system.<sup>29</sup> Articulation of programme theory—and specifically the elucidation of assumptions embedded in it—will identify potential intermediate bottlenecks in the implementation process: what they are, how they operate and what can be done to remove them. Addressing these bottlenecks is crucial for the successful national scale up of the initiative.
2. This research will provide independent, high-quality, empirical evidence of the effectiveness of the SBM-R (RH) initiative in improving the quality of maternity care in facilities, measured by the proportion of performance standards that meet 80% of verification criteria in the three service areas: ANC labour and childbirth and PNC. It will provide empirical evidence of the gap, if any, between the desired and actual health outcomes, besides verifying the quality of the facility data.
3. The research will map out, in detail, the facilitators and barriers to the effective implementation of the SBM-R(RH) initiative. We foresee three inter-related and overlapping perspectives emerging:
  - 3.1 Perspectives of the policymakers/manager: this might include issues of resources—financial, human and equipment, issues of power and authority, issues of organisational structures, management’s receptiveness to change, and whether the initiative fits in with management personnel’s professional and personal goals.
  - 3.2 Perspectives of healthcare providers: the fundamental premise of the SBM-R(RH) initiative is that the healthcare providers assess their own work, that of their colleagues and peers, and that of the organisation, as they strive to meet performance standards of care. Although this approach is intuitively appealing, it requires appropriate and transparent communication between peers and managers, transparent and respectful decision-making processes, and a receptiveness to change by all involved. Issues in any of these areas and the ways in which they may be hampering SBM-R(RH) implementation will be brought forth in the present research. It will also map out the ‘culture of quality of care’ in terms of prevailing values and beliefs of the health providers.
  - 3.3 Perspectives of women and their families: the research will map women’s understanding of quality of care, an important element to consider because care that may be deemed of high quality against recognised standards of care may be unacceptable to women. It will also provide women and their families understanding of the reasons for the suboptimal implementation of the SBM-R(RH) initiative.



**Table 1** Summary of research objectives and methods

Research objectives	Module	Methods
1. Develop a programme theory of the SBM-R(RH) initiative and identify both explicit and implicit assumptions embedded within it	Module 1	Document review and in-depth interviews with key informants among national and district-level policymakers and programme managers
2. Identify the gaps between the SBM-R(RH) programme and the ground reality across the range of contexts that characterise the Malawian healthcare landscape	Modules 2 and 3	1. Quantitative measure of MIPS, using MOH checklists 2. Exit interviews 3. Participation observation, formal and informal interviews and focus group discussions
3. Co-produce and test potential solutions to improve the effective implementation of the SBM-R(RH) initiative to enhance quality and equity of care provided in the health centres	Module 4	Identification and piloting of potential routes to enhancing enablers and/or circumventing current obstacles. The exact methods will depend on the finding from the first 3 modules.
4. Identify routes through which an equity dimension can be embedded within the SBM-R(RH) initiative	Modules 1–4	Development of Policy and Programming Research Advisory Group and Patient and Public Involvement Group. These groups will be continuously and actively engaged through all the phases of the project through one-on-one informal meetings and 4 formal knowledge exchange meetings scheduled at key points of the 5-year project.
5. Develop enhanced interdisciplinary research capacity in the emerging field of implementation research, in Malawi, Kenya and Canada	Modules 1–4	Research staff and two graduate students from Malawi and one postdoctoral student in Canada will be trained over the duration of the project.

MIPS, MOH's Integrated Performance Standards for Reproductive Health; MOH, Ministry of Health; SBM-R(RH), Standards Based Management-Recognition for Reproductive Health.

4. The research will generate knowledge of strategies to enhance the facilitators and address the barriers to effective implementation of the SBM-R(RH) initiative as it is scaled up. We foresee the research providing:
  - 4.1 Guidance of what shifts are required in administrative practices, resources, training and accountability. This may include addressing resource issues (human, financial and equipment) and leadership skills (power and authority, teamwork, role clarity, inclusive decision-making).
  - 4.2 Ways in which a 'culture of quality of care' and 'equity' can be developed. Some possibilities include strategies for increasing staff awareness and commitment to quality, increasing their sensitivity to insidiousness of inequities and how they can mitigate the inequities.
5. The research will inject the inequity agenda in the SBM-R(RH) initiative. Currently, the initiative is silent on inequities related to social-economic class, ethnicity, race, religion and other axes of inequality. This research will generate new knowledge and highlight gaps on equities in the SBM-R(RH) initiative. This may include developing indicators that measure how woman-friendly the quality of care is, as well as gendered equities in healthcare providers, such as gender differentials in pay and benefits.
6. Most of the challenges in Malawi are similar to those in other countries, and we postulate the evidence generated by this research will be applicable in contexts beyond the boundaries of Malawi.
7. The research will contribute to the theoretical advances in the development of the science of implementation research. The present research draws on multiple methods to explore the challenges of implementation of an initiative at the intersection of two complex fields: quality of care and maternal health. We foresee methodological challenges, the addressing of which will produce new learnings and contribute advances in implementation research.
8. An important element of our research is capacity building in the emerging field of implementation research. Despite progress, the chasm between quantitative and qualitative research methods remains large. Policymakers, in particular, while appreciating the 'soft intelligence' that emerges from qualitative studies, struggle to collate and interpret qualitative data in a way that fits with their notions of 'valid' and 'reliable' evidence. The present research will provide an opportunity for Malawian and Canadian students to not only learn interdisciplinary, mixed-methods implementation research, but also to produce a legacy by training a new generation of researchers skilled in conducting qualitative and mixed methods research.

### STRATEGY FOR RESEARCH UPTAKE

Engaged scholarship is a key element of this research and will be anchored in the Canadian Institute of Health Research Integrated Knowledge Translation Framework.<sup>30</sup>

## Target audience

A central feature of this project is to bring together knowledge users from all levels of the health system: consumers, healthcare providers, policymakers and managers. To operationalise this, two bodies will be created:

I. *Policy and Programming Research Advisory Group (PPRAG)* at the healthcare system level. PPRAG will include 5–7 people who will be drawn from the following:

1. The QATWG. This is an existing national level body that is responsible for providing policy guidance on quality assurance matters. It consists of:
  - 1.1 The MOH: this includes the leadership of the directorates of Reproductive Health, Planning and Policy development, and Research. The directors of Clinical Services, Nursing Services and Human Resources will be invited to join this team.
  - 1.2 Regulatory bodies (Nurses and Midwives Council of Malawi, Medical Council of Malawi).
  - 1.3 Stakeholders implementing or supporting quality assurance initiatives (Jhpiego).
2. Health Policy-Research Organization (East Africa).
3. A representative from CHAM.

II. *Patient and Public Involvement Group (PPIG)* to represent the voice of women in the research. This will consist of members of civil society, specifically women who have given birth, parliamentarians and civil society groups that represent women's interests (White Ribbon Alliance).

## Involvement strategies

1. PPRAG involvement will include: (1) ensuring the research design meets their policy, programme and information needs (already accomplished); (2) input in development of data collection tools; (3) data collection support; (4) validation of research findings and (5) translation of research findings into policy and programmatic tasks that will address the issues limiting optimal implementation of the SBM-R(RH) initiative. Members of PPRAG will be continuously and actively engaged through all the phases of the project via one-on-one informal meetings and four formal knowledge exchange meetings scheduled at key points of the 5-year project.
2. PPIC involvement will ensure that researchers are asking the right questions, and are conducting research in ways that are respectful and likely to generate good data. PPIC's engagement will consist of one-on-one informal meetings, development of good interpersonal relationships and formal knowledge exchange meetings. Given this group of people are non-experts, careful use of language will be ensured. The research findings will also be presented at conferences and published in peer-reviewed journals.

## ETHICS

Ethics approval has been obtained from the Malawi National Health Sciences Research Committee

(NHSRC), and the University of Alberta Research Ethics and Management Online (REMO) Board.

Voluntary and informed participation, confidentiality and safety of participants will constitute key principles of researcher–respondent interaction. Written consent will be obtained from policymakers, programme managers and providers. However, oral consent may need to be taken from women and men who will be interviewed in module 3 since educational levels are low in rural areas.

Data security of qualitative and quantitative data will be ensured by (1) uploading the data to a password-protected Google Cloud account. Only the research team will have access to the password. All members of the team will sign a confidentiality agreement. On completion of this study, all data electronic files on the Google Cloud account will be deleted. (2) All participants will be assigned a code, which will be delinked from their identity at data entry point.

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# Improving the standards-based management: recognition initiative to provide high-quality, equitable maternal health services in Malawi. An implementation research protocol

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